

2006--07

**Immunizers' Question & Answer Guide
to Medicare Coverage of
Influenza and Pneumococcal
Vaccinations**

**Steps to Promoting Wellness
Adult Immunizations**

The issues involved in Medicare billing and administration can be complex and may vary state to state. For this reason, we recommend that you contact your local fiscal intermediary, carrier (Part B), or the Centers for Medicare & Medicaid Services' Regional Office Influenza Coordinators for more detailed information.

**Centers for Medicare & Medicaid Services
Dallas Regional Office
Suite 827
1301 Young Street
Dallas, TX 75201**

Table of Contents

A.	Introduction.....	4
	Purpose	
	Background of Medicare Pneumococcal and Influenza Vaccination	
	Benefits	
	ACIP Guidelines	
	Summary of ACIP Guidelines (Pneumococcal/Influenza)	
	Who Should BE Vaccinated?	
	Who Should NOT Get the Influenza Vaccine	
	Other Vaccination Recommendations – Use of Live, Attenuated Influenza Vaccine (LAIV)	
	Contacts/Resources for More Information	
B.	Coverage Policy.....	13
	Coverage Criteria	
	Eligibility	
	Medicare Requirement for Consent	
	Who Can Bill	
	Who to Bill	
	Physician Presence	
	Frequency	
	Home Health Agencies	
	HHA Mass Billers	
C.	Payment Policy.....	21
	Medicare Vaccine/Administration Payment	
	Current Administration and Vaccine Reimbursement Rates	
	Collecting Payment	
	Billing Procedures	
	Home Health Agencies	
	HIPAA	
	Part A - Intermediaries	
	Part B – Carriers	
	Diagnosis & Procedure Codes	
D.	Mass Immunizers/Roster Billers.....	39
	Purpose	
	Enrollment Requirements	
	Billing Procedures	
	Hospital Inpatient Roster Billing	

Table of Contents Continued

E.	Centralized Billing.....	47
F.	Managed Care.....	51
G.	Terms and Definitions.....	53

A. Introduction

Purpose

This document addresses immunizers' commonly asked questions about the administration of influenza and pneumococcal vaccines to Medicare patients. It also includes questions and answers that are particularly relevant to the 2006-07 influenza immunization season.

The following information will be useful for immunizers; however, the issues involved in Medicare billing and administration can be complex and may vary from state to state. For additional, detailed information, contact your local fiscal intermediary, carrier (Part B), or the Centers for Medicare & Medicaid Services (CMS).

The following sections provide a summary of the current recommendations of the Advisory Committee on Immunization Practices (ACIP) as they relate to adult immunization; Medicare coverage and payment policy; requirements for mass immunizers and centralized billing; and a brief discussion of managed care. In addition, a list of definitions is included.

Background of Medicare Pneumococcal and Influenza Vaccination Benefits

Epidemics of influenza are responsible for an average of approximately 36,000 deaths per year in the U.S., of which more than 90 percent occur among those aged 65 or older. Invasive pneumococcal infection (e.g., sepsis, meningitis) causes an estimated 40,000 cases and over 4,000 deaths annually in the U.S. Most deaths due to pneumococcal disease occur in persons aged 65 and older.

The U.S. Congress established the Medicare program in 1965. Coverage for individual preventive services has been added since 1980, and use of preventive services has increased over time. These preventive services include vaccinations against: invasive pneumococcal disease, hepatitis B, and influenza. The Medicare program has covered pneumococcal polysaccharide vaccine (PPV) and its administration since July 1, 1981. Coverage for the influenza vaccine and its administration was added May 1, 1993.

Coverage rates for influenza and pneumococcal vaccines among those aged 65 and older increased substantially in the 1990s, but appear to have plateaued in recent years. In 2003, the Centers for Disease Control and Prevention (CDC) reported that 55.7 percent of persons aged 65 years and older had received a lifetime pneumococcal vaccine. In 2003, influenza immunization rates for this group were 65.6 percent – nearly double the immunization rate in 1989 of 33 percent. The Leading Health Indicators established by the Department of Health and Human Services' Healthy People 2010 target vaccination rates for both vaccines to reach 90 percent for persons aged ≥ 65 years.

The pneumococcal coverage data for 2004 indicate age-adjusted coverage for those ≥ 65 years of 57.0%, and for influenza vaccination, of 64.7% (http://www.cdc.gov/nchs/data/nhis/earlyrelease/200606_05.pdf, and http://www.cdc.gov/nchs/data/nhis/earlyrelease/200606_04.pdf)

ACIP Guidelines

Clinicians should refer to published guidelines for current recommendations related to immunization. ACIP is the only entity within the federal government that makes written recommendations for routine administration of vaccines to pediatric and adult populations. The Infectious Diseases Society of America and the American Thoracic Society also discuss vaccination in their guidelines. At the time of this writing, the most recent ACIP Recommendations for the Prevention of Pneumococcal Disease were published in the April 4, 1997 Morbidity and Mortality Weekly (MMWR). The ACIP influenza immunization guidelines for 2006 were published electronically on June 28, 2006, and are available at <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr55e628a1.htm>.

State laws governing who may administer pneumococcal and influenza vaccines and how the vaccines may be transported vary widely. In addition to staying abreast of current guidelines, CMS urges providers and suppliers to stay current with state immunization regulations.

Summary of ACIP Guidelines

Pneumococcal

ACIP recommends that all persons receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 is recommended to receive another dose after they turn age 65, after 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally an once-in-a-lifetime vaccine after age 65 that can be given at any time of the year. All persons whose vaccination status is unknown should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm).

According to ACIP, pneumococcal vaccine is recommended for the following groups of persons who are at increased risk from invasive pneumococcal disease or its complications:

- Children less than 2 years of age (pneumococcal conjugate vaccine) and adults aged 65 or more (polysaccharide vaccine);
- Adults who have chronic cardiovascular diseases (e.g., congestive heart failure or cardiomyopathy), chronic pulmonary diseases (e.g., chronic obstructive pulmonary disease or emphysema), or chronic liver diseases (e.g., cirrhosis);
- Adults with diabetes mellitus. Diabetes is associated with cardiovascular or renal dysfunction, both of which increase the risk for severe pneumococcal illness;

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- Persons who have chronic liver disease;
 - Persons who have alcoholism;
 - Persons with functional or anatomic asplenia (e.g., sickle cell disease or splenectomy). This group is at very high risk for pneumococcal infection, because this condition leads to reduced clearance of encapsulated bacteria from the bloodstream.
 - Persons with cerebrospinal fluid leakage resulting from congenital lesions, skull fractures, or neurosurgical procedures. These persons are at risk for recurrent pneumococcal meningitis;
 - Persons who have decreased responsiveness to polysaccharide antigens or an increased rate of decline in serum antibody concentrations as a result of
 - a) Immunosuppressive conditions (e.g., congenital immunodeficiency, human immunodeficiency virus [HIV] infection, leukemia, lymphoma, multiple myeloma, Hodgkin's disease, or generalized malignancy). *S. pneumoniae* is the most commonly identified bacterial pathogen that causes pneumonia in HIV-infected persons;
 - b) Organ or bone marrow transplantation;
 - c) Chemotherapy with alkylating agents, antimetabolites, or systemic corticosteroids;
 - d) Systemic corticosteroids; or
 - e) Chronic renal failure or nephrotic syndrome.

About 78% of adults who have invasive pneumococcal infection have at least one of the previously mentioned underlying medical conditions, including age greater than or equal to 65 years.

Because asthma has not been associated with an increased risk for pneumococcal disease, persons with asthma do not need pneumococcal vaccine unless they have asthma as part of chronic bronchitis or emphysema or they use long-term systemic corticosteroids.

Influenza

Primary Changes and Updates in the 2006--2007 Recommendations

The 2006 recommendations include six principal changes or updates:

- ACIP recommends that healthy children aged 24--59 months and their household contacts and out-of-home caregivers be vaccinated against influenza (see Target Groups for Vaccination). This change extends the recommendations for vaccination of children so that all children aged 6--≤59 months receive annual vaccination.
- ACIP emphasizes that all children aged 6 months--<9 years who have not been previously vaccinated at any time with either live, attenuated influenza vaccine (LAIV) or trivalent inactivated influenza vaccine (TIV) should receive 2 doses of vaccine. Those children aged 6 months--≤9 years who receive TIV should have a booster dose of TIV administered ≥1 month after the initial dose, before the onset of

influenza season, if possible. Those children aged 5-- \leq 9 years who receive LAIV should have a second dose of LAIV 6--10 weeks after the initial dose, before the influenza season, if possible. If a child aged 6 months-- \leq 9 years received influenza vaccine for the first time during a previous season but did not receive a second dose of vaccine within the same season, only 1 dose of vaccine should be administered this season (see Efficacy and Effectiveness of Inactivated Influenza Vaccine, Children; TIV Dosage; and LAIV Dosage and Administration).

- To ensure optimal use of available doses of influenza vaccine, projected to be approximately 100 million doses, health-care providers, those planning organized campaigns, and state and local public health agencies should 1) develop plans for expanding outreach and infrastructure to vaccinate more persons than during the previous year and 2) develop contingency plans for the timing and prioritization of administering influenza vaccine, if the supply of vaccine is delayed and/or reduced because of the complexity of the production process (see Influenza Vaccine Supply and Timing of Annual Influenza Vaccination).
- ACIP emphasizes that influenza vaccine should continue to be offered throughout the influenza season even after influenza activity has been documented in a community. In addition, ACIP encourages all community vaccinators and public health agencies to schedule clinics that serve target groups and to help extend the routine vaccination season by offering at least one vaccination clinic in December (see Influenza Vaccine Supply and Timing of Annual Influenza Vaccination).
- ACIP recommends that neither amantadine nor rimantadine be used for the treatment or chemoprophylaxis of influenza A in the United States because of recent data indicating widespread resistance of influenza virus to these medications (23, 24). Until susceptibility to adamantines has been re-established among circulating influenza A viruses, oseltamivir or zanamivir may be prescribed if antiviral treatment or chemoprophylaxis of influenza is indicated (see Recommendations for Using Antiviral Agents for Influenza).
- The 2006--07 trivalent vaccine virus strains are A/New Caledonia/20/1999 (H1N1)-like, A/Wisconsin/67/2005 (H3N2)-like, and B/Malaysia/2506/2004-like antigens. For the A/Wisconsin/67/2005 (H3N2)-like antigen, manufacturers may use the antigenically equivalent A/Hiroshima/52/2005 virus; for the B/Malaysia/2506/2004-like antigen, manufacturers may use the antigenically equivalent B/Ohio/1/2005 virus (see Influenza Vaccine Composition).

Who Should Be Vaccinated?

Persons at Increased Risk for Complications

Vaccination with inactivated influenza vaccine is recommended for the following persons who are at increased risk for complications from influenza:

- Persons aged ≥ 65 years;
- Residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- Adults and children who have required regular medical follow-up or hospitalization during the preceding year because of chronic metabolic diseases (including diabetes mellitus), renal dysfunction, hemoglobinopathies, or immunosuppression (including immunosuppression caused by medications or by HIV);
- Adults and children who have any conditions (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk of aspiration;
- Children and adolescents (aged 6 months-18 years) who are receiving long-term aspirin therapy and, therefore, might be at risk for experiencing Reye syndrome after influenza infection;
- Women who will be pregnant during the influenza season; and
- Children aged 6-59 months.

Other Target Groups

- Persons 50-64 years of age,
- Persons who can transmit influenza to those at high risk,
- Healthcare workers.

For more details regarding target populations for vaccination, see the link to the ACIP recommendations for “Prevention and Control of Influenza.”

Healthcare Workers

All healthcare workers should be vaccinated against influenza annually. Facilities that employ healthcare workers are strongly encouraged to provide vaccine to workers by using approaches that maximize vaccination rates. This will protect healthcare workers, their patients, and communities, and will improve prevention of influenza-associated disease, patient safety, and will reduce disease burden. Influenza vaccination rates among healthcare workers should be regularly measured and reported. Although vaccination rates for healthcare workers are about 40%, with moderate effort, organized campaigns can attain higher rates of vaccination among this population.

Currently, seven states have legislation requiring annual influenza vaccination of healthcare workers or the signing of an informed declination, and 15 states have

regulations regarding vaccination of healthcare workers in long-term care facilities. Physicians, nurses, and other workers in both hospital and outpatient-care settings, including medical emergency response workers (e.g., paramedics and emergency medical technicians), should be vaccinated, as should employees of nursing home and chronic-care facilities who have contact with patients or residents.

“The ACIP, with CDC’s Healthcare Infection Control Practices Advisory Committee (HICPAC) issued recommendations calling for urgent attention to influenza vaccination of health care workers (see <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>). These in particular recommend that healthcare institutions

- Educate HCP regarding the benefits of influenza vaccination and the potential health consequences of influenza illness for themselves and their patients, the epidemiology and modes of transmission, diagnosis, treatment, and no vaccine infection control strategies, in accordance with their level of responsibility in preventing health-care--associated influenza (category IB).
- Offer influenza vaccine annually to all eligible HCP to protect staff, patients, and family members and to decrease HCP absenteeism. Use of either available vaccine (inactivated and live, attenuated influenza vaccine [LAIV]) is recommended for eligible persons. During periods when inactivated vaccine is in short supply, use of LAIV is especially encouraged when feasible for eligible HCP (category IA).
- Provide influenza vaccination to HCP at the work site and at no cost as one component of employee health programs. Use strategies that have been demonstrated to increase influenza vaccine acceptance, including vaccination clinics, mobile carts, vaccination access during all work shifts, and modeling and support by institutional leaders (category IB).
- Obtain a signed declination from HCP who decline influenza vaccination for reasons other than medical contraindications (category II).
- Monitor HCP influenza vaccination coverage and declination at regular intervals during influenza season and provide feedback of ward-, unit-, and specialty-specific rates to staff and administration (category IB).
- Use the level of HCP influenza vaccination coverage as one measure of a patient safety quality program (category II).

In addition, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has issued a standard requiring that critical access hospitals, hospitals, and long-term care facilities to offer influenza vaccine to their employees (see http://www.jointcommission.org/NewsRoom/NewsReleases/nr_06_13_06.htm). The standard goes into effect January 1, 2007.”

Who Should Not Be Vaccinated

People in the following groups should not get an influenza vaccine before talking with their doctor:

- People who have a severe allergy (i.e., anaphylactic allergic reaction) to hens' eggs or to components of the vaccine or prior adverse reaction following influenza vaccination; and
- Persons who previously developed Guillain-Barre Syndrome within 6 weeks after getting the influenza shot.

Other Vaccination Recommendations for persons ≥ 65 years –Use of Live, Attenuated Influenza Vaccine (LAIV)

- Healthy persons who are 5-49 years of age and not pregnant may use the LAIV. This includes healthcare workers (except those who care for severely immunocompromised patients in special care units), out-of-home caregivers and household contacts of persons in high-risk groups (e.g., persons aged ≥ 65 years; persons with chronic conditions such as diabetes, heart or lung disease, or weakened immune systems because of illness or medication; and children aged ≤ 2 years). The LAIV is administered intranasally.

Persons in priority groups identified above should be encouraged to search locally for vaccine if their usual healthcare provider does not have vaccine available.

Many children aged < 9 years require two doses of vaccine if they have not previously been vaccinated. All children at risk of complications from influenza, including those aged 6-23 months, who present for vaccination should be vaccinated with a first or second dose, depending on vaccination status. However, doses should not be held in reserve to ensure that two doses will be available. Rather, available vaccine should be used to vaccinate persons in priority groups on a first-come first- served basis.

Contacts/Resources for More Information

Influenza Vaccination of Health-Care Personnel

Recommendations of the Healthcare Infection Control Practices Advisory Committee (HICPAC) and the ACIP <http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm>.

ACIP Guidelines

ACIP Recommendations List, <http://www.cdc.gov/nip/publications/ACIP-list.htm>
ACIP Recommendations for the Prevention of Pneumococcal Disease, MMWR, April 4, 1997, www.cdc.gov/mmwr/preview/mmwrhtml/00047135.htm (html),

CMS Web Site

<http://www.cms.hhs.gov/AdultImmunizations/>

CDC Web Sites

<http://www.cdc.gov/nip> (National Immunization Program)

<http://www.cdc.gov/influenza> (CDC Influenza Influenza)

http://www.cdc.gov/mmwr/?s_cid=mmwr_online_e (Morbidity and Mortality Weekly Reports)

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5502a1.htm?s_cid=rr5502a1_e
(Influenza Vaccination of Health-Care Personnel)

Medicare Learning Network (MLN)

MLN Preventive Services Educational Products web page located at http://www.cms.hhs.gov/MLNProducts/35_PreventiveServices.asp#TopOfPage. At this page providers will find all MLN educational products related to flu and all other Medicare Preventive Services

An Overview of Medicare Preventive Services for Physicians, Providers, Suppliers, and Other Health Care Professionals

http://www.cms.hhs.gov/MLNProducts/04_Multimedia.asp#TopOfPage

Medicare Prevention Services Series: Part 1 Adult Immunizations Web-based Training Course (Updated 8/2006)

http://cms.meridianksi.com/kc/main/kc_frame.asp?kc_ident=kc0001&loc=5

Medicare Preventive Services Brochure: Adult Immunizations

http://cms.hhs.gov/MLNProducts/Downloads/adult_immunization_06-08-05.pdf

Pandemic Influenza

<http://www.pandemicinfluenza.gov>.

CMS Manuals and Transmittals

Modification of Roster Billing for Mass Immunizers Billing for Inpatient Part B Services (Types of Bills (TOB) 12X – 22X

<http://cms.hhs.gov/Transmittals/downloads/R829CP.pdf>

Medicare Claims Processing Manual, Chapter 18 – Preventive and Screening Services

<http://www.cms.hhs.gov/manuals/downloads/clm104c18.pdf>

Pub 11 – Home Health Agency

<http://www.cms.hhs.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS021914>

Intermediary-Carrier Directory

http://www.cms.hhs.gov/ContractingGeneralInformation/Downloads/02_ICdirectory.pdf

MedQIC Immunization Toolkit

<http://www.medqic.org/dcs/ContentServer?cid=1105558764854&pagename=Medqic%2FMQTools%2FToolTemplate&parentName=Topic&c=MQTools>

Forms

CMS Paper Forms (1450 and 1500) and Instructions (at

http://new.cms.hhs.gov/ElectronicBillingEDITrans/15_1450.asp

Form CMS-855-I <http://www.cms.hhs.gov/CMSforms/downloads/cms855i.pdf>

Form CMS-B

<http://www.cms.hhs.gov/CMSforms/downloads/cms855b.pdf>

B. Coverage Policy

Coverage Criteria

B.1 What are Medicare's coverage criteria for influenza vaccinations?

Effective for services performed on or after May 1, 1993, Medicare will pay for influenza virus vaccines and their administration. Generally, only one influenza virus vaccination is medically necessary per influenza season. Medicare beneficiaries may receive the vaccine **once each influenza season, paid by Medicare**, without a physician's order and without the supervision of a physician. A patient could receive influenza vaccine twice in a calendar year (two different influenza seasons) and the provider would be reimbursed for each. However, state laws regarding who can administer vaccines still apply. The Medicare Part B deductible and coinsurance do not apply. Additional vaccination may be covered if medically necessary.

B.2 What are Medicare's coverage criteria for Pneumococcal Polysaccharide Vaccine (PPV) vaccinations?

Effective for services performed on or after May 1, 1981, Medicare began paying for PPV and its administration. Effective for claims with dates of service on or after July 1, 2000, Medicare no longer requires the PPV to be ordered by a doctor of medicine or osteopathy. However, state laws regarding who can administer vaccines, and under what circumstances, still apply. When allowable under state law, a beneficiary may receive the vaccine upon request without a physician's supervision.

In accordance with ACIP recommendations, all persons should receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 are recommended to receive another dose after they turn age 65, once 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally an once-in-a-lifetime vaccine after age 65 vaccination that can be given at any time during the year. All persons whose vaccine status is unknown should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm).

Persons 65 years of age or older and immunocompetent adults who are at increased risk of pneumococcal disease or its complications because of chronic illness are considered at high risk.

Provided that at least five years have passed since receipt of a previous dose of PPV vaccine, revaccination may be administered only to persons at highest risk of serious pneumococcal infection and those likely to have a rapid decline in pneumococcal antibody levels. This group includes persons with functional or anatomic asplenia (e.g., sickle cell disease, splenectomy), human immunodeficiency virus (HIV) infection, leukemia, lymphoma, Hodgkin's disease, multiple myeloma, generalized malignancy,

chronic renal failure, nephrotic syndrome, or other conditions associated with immunosuppression, such as organ or bone marrow transplantation, and those receiving immunosuppressive chemotherapy. Routine revaccination of people age 65 or older is not appropriate, unless determined medically necessary by a physician, unless initial vaccination was given before age 65, and 5 years has passed. Additional vaccine during an influenza season may be covered if medically necessary.

B.3 Could you provide clarification regarding the “when in doubt rule” concerning re-vaccination of Medicare patients with the pneumonia vaccine when they don’t remember if they have been vaccinated?

Persons aged 65 years or more should be administered a second dose of vaccine if they received the vaccine more than 5 years previously and were less than 65 years at the time of primary vaccination. Persons aged 65 years or older with unknown vaccination status should be administered one dose of vaccine.

B.4 Will Medicare pay for vaccination if an individual cannot produce documentation or is not sure whether they have received a PPV shot?

Yes. Those administering the vaccine should not require the patient to present an immunization record prior to administering PPV, nor should they feel compelled to review the patient’s complete medical record if it is not available. Instead, provided that the patient is competent, health professionals may rely on the patient’s verbal history to determine prior vaccination status. If the patient is uncertain about their vaccination history in the past five years, the vaccine should be given. However, if the patient is certain he/she was vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given and that more than five years have passed since receipt of the previous dose, revaccination is not appropriate unless the patient is at highest risk.

B.5 Will Medicare pay for the revaccination if an individual, not at highest risk, is revaccinated for PPV?

Yes, if a beneficiary who is not at highest risk is revaccinated because of uncertainty about his or her vaccination status, Medicare will cover the revaccination.

Eligibility

B.6 Is a person with only Part A coverage entitled to receive the influenza and PPV vaccinations and have them covered under Part B?

No. The influenza and PPV vaccines and their administration are a Part B covered service only. A person’s eligibility for Part B coverage is indicated on their social security card. Medicare Card clearly displays Part A and/or Part B.

B.6a. If a person has other insurance, do I need to bill that other insurance company first for influenza and pneumococcal vaccinations?

No. Medicare is considered the primary payer for influenza and PPV vaccinations.

Who Can Bill?

B.7 Which individuals and what entities may bill Medicare for the influenza and PPV vaccines and their administration?

Any individual or entity meeting state licensure requirements may qualify to have payment made for furnishing and administering the influenza and PPV vaccines to Medicare beneficiaries enrolled under Part B.

B.8 May a registered nurse/pharmacist employed by a physician/pharmacy use the physician's/pharmacy's provider number if the nurse/pharmacist in a location other than the physician's office/pharmacy provides influenza and PPV vaccinations?

No. If the nurse/pharmacist is not working for the physician/pharmacy when the services are provided (e.g., a nurse/pharmacist is "moonlighting," administering influenza and PPV vaccinations at a shopping mall (under protocol) and not as an employee of the physician/pharmacy), the nurse/pharmacists may obtain a provider number and bill the carrier directly. However, if the nurse/pharmacist is working for the physician/pharmacy when the services are provided, the nurse/pharmacist would use the physician's/pharmacy's provider number.

Who to Bill

B.9 What types of providers and suppliers may bill the intermediary for the influenza and PPV vaccinations (CR 4240, Chapter 18)?

The following participating providers of services may bill intermediaries for this benefit:

Hospitals (including Critical Access Hospitals (CAHs), Indian Health Service hospitals (IHS); and IHS CAHs)
Skilled Nursing Facilities (SNFs);
Certified Home Health Agencies (HHAs);
Comprehensive Outpatient Rehabilitation Facilities (CORFs);
Outpatient Physical Therapy (OPT)
Independent and Hospital-Based Renal Dialysis Facilities (RDFs).

B. 10 May Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs) bill the intermediary for the influenza and pneumococcal vaccinations.

RHCs and FQHCs do not bill the intermediary for the influenza and pneumococcal vaccinations. Payment is made based on information provided on the cost report.

B.11 What type of providers and suppliers may bill the carrier for influenza and PPV vaccinations?

Physicians
Suppliers
Hospices
Public Health Clinics
Pharmacists /Pharmacies
Self Employed Nurses
Senior Centers*
Shopping Malls*
Non Skilled Nursing Homes
Assisted Living Facilities
Mass Immunization Providers
Non-certified HHAs*

* These are possible locations where a mass immunization provider may provide vaccination services.

B.12 May a non-participating provider submit a bill for the patient or get paid for vaccine cost from the fiscal intermediary?

No. A non-participating provider would not bill Part A (inpatient services) for influenza and pneumococcal immunizations. The provider would bill the carrier for professional Part B services.

B.13 May certified institutional providers submit claims to a carrier?

No. With the exception of hospice providers, certified institutional providers must bill their intermediary for this Part B benefit. Hospice providers bill the carrier.

B.14 How should nonparticipating provider facilities (e.g., nursing homes) bill Medicare?

Non-Medicare-participating provider facilities bill their local carrier.

B.15 May Home Health Agencies (HHAs) that have a Medicare-certified component and a non-Medicare certified component elect to furnish influenza and PPV benefit through the non-certified component and bill the Part B carrier?

Yes, for certain circumstances. See 473. Billing for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines at

<http://www.cms.hhs.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS021914> (hha_460 to 473). When an HHA provides the influenza vaccine in a mass immunization setting, it does not have the option to choose who to roster bill for this service. If the service is being provided by employees from the certified portion, and as a result, reports the costs on the cost report, you must bill its Regional Home Health Intermediary (RHHI) on the Form CMS-1450.

If employees from the non-certified portions (employees of another entity that is not certified as part of the HHA) are providing the service and as a result, payment will not be made on the cost report for these costs, the HHA must obtain a provider number and bill its carrier on the Form CMS-1500.

If employees from both certified and non-certified portions of your facility are used to furnishing the vaccine at a single mass immunization site, the HHA must prepare two separate rosters, i.e., one for employees of the certified portion of the facility to be submitted to your RHHI, and one for employees of the non-certified portion of the facility to be submitted to the carrier.

B.16 How do carriers handle influenza and PPV vaccination claims for Railroad Retirement Board (RRB) beneficiaries? Who should be billed for these services?

Carriers will return as unprocessable assigned claims and deny unassigned claims. The physician, non-physician practitioner or supplier must submit the claim to Palmetto GBA (the RRB carrier) at P.O. Box 10066, Augusta, GA 30999.

Physician Presence /Order

B.17 Does a physician have to be present when the influenza and PPV vaccines are administered?

No. Medicare does not require a physician to be present. However, laws in individual states may require a physician's presence.

B.18 Is a physician order (written or verbal), plan of care, or any other type of physician involvement required for Medicare coverage of the influenza and PPV vaccinations?

No. For Medicare coverage purposes, it is no longer required that either of the vaccines be ordered by a doctor of medicine or osteopathy though individual state law may require a physician order or other physician involvement. Therefore, when allowable under state law, the beneficiary may receive the vaccines upon request without a physician's or osteopath's order.

Frequency

B.19 There has been some confusion about how often a beneficiary can receive an influenza vaccination and have it covered by Medicare. If a beneficiary receives an influenza vaccination more than once in a 12-month period, will Medicare still pay for it?

Yes. Generally, Medicare pays for one influenza vaccination per influenza season. Medicare beneficiaries may receive the vaccine **once each influenza season, paid by Medicare**, without a physician's order and without the supervision of a physician. A patient could receive an influenza vaccine twice in a calendar year (two different influenza seasons) and the provider would be reimbursed for each. For example, a beneficiary may receive an influenza vaccination in January 2006 for the 2006--07 influenza season and another influenza vaccination in November 2006 for the 2007--08 influenza season. In this case, Medicare will pay for both vaccinations because the beneficiary received only one influenza vaccination per season (January and November).

B.20 What if a beneficiary needs more than one influenza vaccine in an influenza season?

Medicare will pay for more than one influenza vaccination per influenza season if a physician determines and documents that the vaccination is reasonable and medically necessary. The administering provider should maintain documentation.

B.21 Will Medicare cover more than one PPV vaccine in a patient's lifetime?

Yes, in accordance with ACIP all persons should receive a dose of pneumococcal vaccine when or after they reach age 65. Persons who receive a dose before age 65 are recommended to receive another dose after they turn age 65, once 5 years have elapsed since their prior dose. The pneumococcal vaccine is generally an once-in-a-lifetime after age 65 vaccination that can be given at any time during the year. All persons who have unknown vaccination status should receive one dose of vaccine. Pneumococcal vaccine may be administered at the same time as influenza vaccine (by separate injection in the other arm).

Home Health Agencies (HHAs)

B.22 Will Medicare pay a HHA for a nurse's visit when he or she goes into a patient's home to furnish the influenza or PPV vaccine?

It depends on the circumstances. If the sole purpose for a HHA visit is to administer a vaccine (influenza, PPV), Medicare will not pay for a skilled nursing visit by an HHA nurse under the HHA benefit. However, the vaccine and its administration are covered under the vaccine benefit. The administration should include charges only for the

supplies being used and the cost of the injection. HHAs are not permitted to charge for travel time or other expenses (e.g., gasoline).

B.23 May HHAs that have a Medicare-certified component and a non-Medicare certified component elect to furnish the influenza and PPV benefit through the non-certified component and bill the Part B carrier?

Yes, for certain circumstances. See 473. Billing for Pneumococcal Pneumonia, Influenza Virus, and Hepatitis B Vaccines at <http://www.cms.hhs.gov/Manuals/PBM/itemdetail.asp?filterType=none&filterByDID=0&sortByDID=1&sortOrder=ascending&itemID=CMS021914> (hha_460 to 473). When you provide the influenza virus vaccine in a mass immunization setting, you do not have the option to pick and choose who to roster bill for this service. If you are using employees from your certified portion, and as a result will be reflecting these costs on your cost report, you must bill your Regional Home Health Intermediary (RHHI) on the Form CMS-1450.

If you are using employees from your non-certified portions (employees of another entity that is not certified as part of your HHA), and as a result, payment will not be made on the cost report for these costs, you must obtain a provider number and bill your carrier on the Form CMS-1500.

If employees from both certified and non-certified portions of your facility are used to furnish the vaccine at a single mass immunization site, you must prepare two separate rosters, i.e., one for employees of the certified portion of your facility to be submitted to your RHHI, and one for employees of the non-certified portion of your facility to be submitted to your carrier.

B.24 Does a physician have to be present when the influenza and PPV vaccines are administered?

No. Medicare does not require a physician to be present. However, laws in individual states may require a physician's presence.

B.25 If the sole purpose for an HHA visit is to administer a vaccine (influenza, PPV, or hepatitis B), will Medicare pay for a skilled nursing visit by an HHA nurse under the HHA benefit?

No, however, the vaccine and its administration are covered under the vaccine benefit. The administration should include charges only for the supplies being used and the cost of the injection. The HHA bills the Health Care Procedure Coding System (HCPCS) code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

B.26 If a vaccine (influenza, PPV, or Hepatitis B) is administered during the course of an otherwise covered home health visit (e.g., to perform wound care), is the visit covered by Medicare?

Yes, the visit would be covered as normal, but the HHA must not include the vaccine or its administration in their visit charge. In this case, the HHA is entitled to payment for the vaccine and its administration under the vaccine benefit. In this situation, the HHA bills under bill type 34X and reports revenue code 0636 along with the appropriate HCPCS code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

B.27 If during a HHA visit a patient's spouse is a Medicare beneficiary and requests an influenza or PPV vaccination, can Medicare be billed?

The vaccine cost and administration is billable along with the supplies, but the visit is not billable for the spouse. The injection may be given at the time of a scheduled visit for the patient.

HHA Mass Billers

Please refer to Section D: Mass Immunizers and Roster Billing

C. Payment Policy

Medicare Vaccine/Administration Payment

The total payment received for administration of influenza and pneumococcal vaccines is based upon:

Cost of Vaccine Reimbursement + Compensation for Vaccine Administration

C.1 Why is there such a variation between states and even within states in Medicare reimbursement rates for influenza and PPV vaccine and its administration?

When billing Medicare Part B for the cost of the vaccine, there should be no variation in Medicare reimbursement. Medicare's payment allowance limits for the influenza and PPV vaccines are 95% of the average wholesale price (AWP) as reflected in such published drug compendia as the Red Book or Medispan.

Since administration fee schedules are adjusted for each Medicare payment locality, there is a variation in the administration payment amount nationwide. Medicare payment by carriers for the administration of the vaccines is linked to payment for services under the physician fee schedule, but is not actually paid under the physician fee schedule. The compensation for the administration is the lesser of the actual charge or the fee schedule amount for a comparable injection (i.e., vaccine administration CPT 90471). This fee schedule is determined each year with an effective date of January 1.

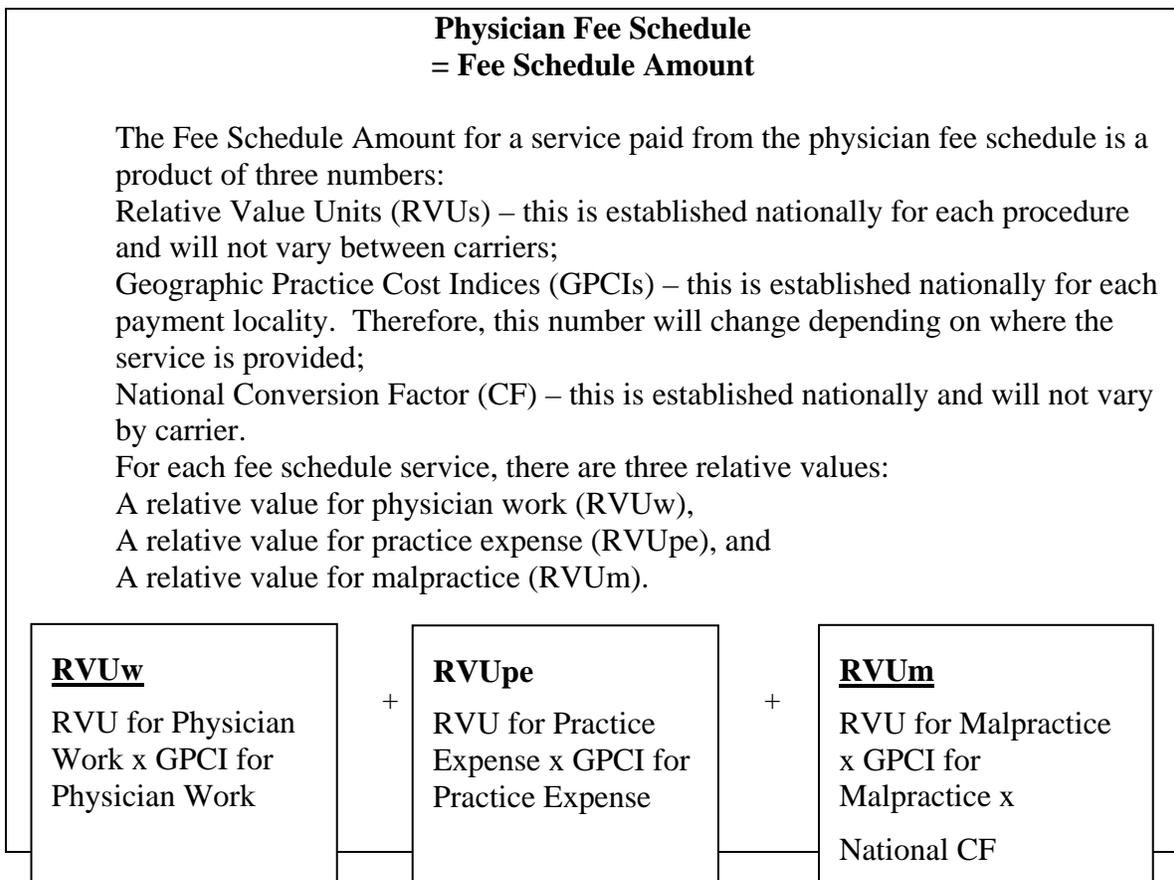
Payments for Drugs and Biologicals
<p>Medicare Part B drugs and biologicals not paid on a cost or prospective payment basis are paid based on the new average sales price (ASP) methodology. The ASP payment methodology is based on quarterly data submitted to Medicare by manufacturers. The payment allowance limits for Medicare Part B drugs and biologicals not paid on a cost or prospective payment basis are 106 percent of the ASP.</p> <p>There are exceptions to this general rule. The payment allowance limits for influenza, PPV, Hepatitis B, blood and blood products, with certain exceptions like blood clotting factors, are 95 percent of the average wholesale price (AWP) as reflected in the published compendia.</p> <p>The payment allowance limits for infusion drugs furnished through a covered item of durable medical equipment (DME) on or after January 1, 2005 are 95 percent of the AWP reflected in the published compendia as of October 1, 2003, regardless or whether or not the DME is implanted.</p>

C.2 When will this year's vaccine reimbursement rate be set?

Since the Medicare vaccine payment rate is based on the AWP for the current year's vaccines, not the AWP for the previous season, carriers cannot calculate this year's payment rate until AWPs are published in sources, such as the Red Book or Medispan. This occurs when the vaccine licenses in the summer. Medicare cannot adjust reimbursement rates until the AWPs are published, but can retroactively adjust claims to September 1.

C.3 How is the payment rates for the administration of the influenza and PPV vaccines determined?

The allowed amount for the administration of the influenza and PPV is based on the same rate as the HCPCS code 90471 (Injection, sc/im) as priced on the physician fee schedule database. When billing Medicare, providers will submit the code G0008 (influenza) or G0009 (pneumococcal) for the administration of vaccine. Therefore, the allowable fee for the administration of the influenza and/or PPV will vary based on the locality of the provider.



Current Administration and Vaccine Reimbursement Rates

Vaccine Administration Rates: The 2006-2007 administration fees paid by Medicare are attached to this document. **The 2007 Allowances provides a list of reimbursement rates for influenza and pneumococcal vaccinations for each state through January 2008.**

NATIONAL FLU BILLER ADMINISTRATION CODES		
JANUARY 1, 2007		
STATE	SERVICE AREA	G0008 & G0009
Alabama	Alabama	\$17.20
Alaska	Alaska	\$20.82
Arizona	Arizona	\$19.27
Arkansas	Arkansas	\$16.88
California	Anaheim/Santa Anna	\$22.65
California	Los Angeles	\$21.63
California	Marin/Napa/Solano	\$23.93
California	Oakland/Berkeley	\$24.45
California	San Francisco	\$26.77
California	San Mateo	\$26.75
California	Santa Clara	\$26.85
California	Ventura	\$21.79
California	Rest of California	\$19.98
Colorado	Colorado	\$19.45
Connecticut	Connecticut	\$21.78
Delaware	Delaware	\$19.61
DC	DC+ MD/VA Suburbs	\$22.91
Florida	Ft. Lauderdale	\$19.45
Florida	Miami	\$20.43
Florida	Rest of Florida	\$18.57
Georgia	Atlanta	\$20.57
Georgia	Rest of Georgia	\$17.64
Hawaii	Hawaii/Guam	\$20.77
Idaho	Idaho	\$17.38
Illinois	Chicago	\$21.48
Illinois	East St. Louis	\$18.81
Illinois	Suburban Chicago	\$21.22
Illinois	Rest of Illinois	\$17.72
Indiana	Indiana	\$17.89

Iowa	Iowa	\$17.43
Kansas	Kansas	\$17.63
Kentucky	Kentucky	\$17.35
Louisiana	New Orleans	\$18.69
Louisiana	Rest of Louisiana	\$17.33
Maine	Southern Maine	\$19.37
Maine	Rest of Maine	\$17.69
Maryland	Baltimore/Surrounding Cntys	\$20.43
Maryland	Rest of Maryland	\$18.98
Massachusetts	Metropolitan Boston	\$23.82
Massachusetts	Rest of Massachusetts	\$20.69
Michigan	Detroit	\$20.93
Michigan	Rest of Michigan	\$18.48
Minnesota	Minnesota	\$19.18
Mississippi	Mississippi	\$17.11
Missouri	Metropolitan Kansas City	\$19.00
Missouri	Metropolitan St. Louis	\$18.72
Missouri	Rest of Missouri	\$16.67
Montana	Montana	\$17.23
Nebraska	Nebraska	\$17.47
Nevada	Nevada	\$19.96
New Hampshire	New Hampshire	\$19.68
New Jersey	Northern New Jersey	\$22.59
New Jersey	Rest of New Jersey	\$21.16
New Mexico	New Mexico	\$17.80
New York	Manhattan	\$23.86
New York	NYC Suburbs/Long Island	\$23.66
New York	Poughkpsie/NYC	\$20.47
New York	Queens	\$22.82
New York	Rest of New York	\$18.13
North Carolina	North Carolina	\$18.15
North Dakota	North Dakota	\$17.33
Ohio	Ohio	\$18.44
Oklahoma	Oklahoma	\$17.18
Oregon	Portland	\$19.91
Oregon	Rest of Oregon	\$18.14
Pennsylvania	Metropolitan Philadelphia	\$20.96
Pennsylvania	Rest of Pennsylvania	\$17.98
Puerto Rico	Puerto Rico	\$15.05
Rhode Island	Rhode Island	\$19.42
South Carolina	South Carolina	\$17.69
South Dakota	South Dakota	\$17.45
Tennessee	Tennessee	\$17.61
Texas	Brazoria County	\$19.06
Texas	Dallas County	\$20.24
Texas	Galveston County	\$18.82
Texas	Harris County	\$19.74
Texas	Jefferson County	\$17.60
Texas	Tarrant County	\$19.23

Texas	Travis County	\$19.95
Texas	Rest of Texas	\$17.60
Utah	Utah	\$18.37
Vermont	Vermont	\$18.74
Virgin Islands	Virgin Islands	\$19.52
Virginia	Virginia	\$18.40
Washington	Seattle (King County)	\$21.10
Washington	Rest of Washington	\$18.99
West Virginia	West Virginia	\$17.14
Wisconsin	Wisconsin	\$18.18
Wyoming	Wyoming	\$17.37

Note: If county is not listed specifically, then the provider is in Locality 99 - Rest of State.

Vaccine Reimbursement Rates may be obtained at http://new.cms.hhs.gov/McrPartBDrugAvgSalesPrice/02_aspfiles.asp - 2006 Average Sales Price (ASP) Drug Pricing Files—Medicare Part B Drug ASP

The rate for the **influenza vaccine is \$12.62** through August 31, 2007.

The rate for the **pneumococcal vaccine is \$27.08** through August 31, 2007.

C.4 Describe the process for updates and changes to the Revisions to Payment Policies. What is legislatively set? What parts can CMS propose changes to?

The formula for determining the update to vaccine administration is statutorily defined. CMS sets the relative value of physician services following long-established processes that are described in Medicare regulations. In general, CMS proposes relative values in May for the following year. The proposed rule has a 60-day comment period. Comments are encouraged and considered before the final rule is issued. The reimbursement for vaccine cost is determined in accordance with statutory guidelines and changes each year based upon published AWP's for each year's licensed vaccines.

C.5 Will Medicare's changes in payment for vaccine administration affect Medicaid payment?

No. Medicaid sets its own payment rate for immunization based on factors other than Medicare payment.

Vaccine /Administration Payment When Billing Fiscal Intermediaries and Carriers

C.6 In the outpatient setting, is the administration payment a set fee no matter what it costs to administer the vaccine (Influenza and PPV)? Where is the regional variability as far as cost for vaccine; is it the administration or the vaccine cost or both?

Effective 1/1/03, payment for vaccines at hospital outpatient departments and HHAs is no longer made under the Outpatient Prospective Payment System (OPPS). Payment is made under reasonable cost not the hospital OPPS. Payment for vaccines at Comprehensive Outpatient Rehabilitation Facilities (CORFs) is made based on the lower actual charge or 95% of the AWP.

For hospital outpatient departments, the payment for administering the vaccine is paid under the hospital outpatient prospective payment system (OPPS). Payment rates for the administration of the vaccine itself (i.e., the injection) and the vaccine vary based on differences in costs across regions. CMS uses the same factor to adjust other services provided under the hospital OPPS. We also note that the payment rate for the administration of the vaccine when provided in a physician's office is also adjusted for geographic differences in costs.

Collecting Payment

Under Section 114 of the Benefits Improvement and Protection Act of 2000 (BIPA), payment for any drug or biological covered under Part B of Medicare may be made only on an assignment-related basis (note: Influenza and Pneumococcal Vaccines are covered under Medicare Part B not Part D). Therefore, all physicians, non-physician practitioners, and suppliers who administer influenza or pneumococcal vaccines after February 1, 2001, must take assignment on the claim for the vaccine.

C.7 Does the limiting charge provision apply to the influenza or PPV benefit?

Yes. All physicians and suppliers, regardless of participation status, must accept assignment of the Medicare vaccine payment rate.

However, non-participating physicians and suppliers who do not accept assignment for the administration of influenza vaccine or PPV benefit may collect their usual charges (i.e., the amount charged a patient who is not a Medicare beneficiary) for influenza vaccine and PPV administration. The beneficiary is responsible for paying the difference between what the physician or supplier charges and the amount Medicare allows for administration.

C.8 Does the 5 percent payment reduction for physicians who do not accept assignment for the administration of the vaccine apply to the influenza and PPV vaccination benefit?

No. Only items and services covered under limiting charge are subject to the 5 percent payment reduction.

If a beneficiary receives an influenza vaccination from a non-participating physician, provider, or supplier who does not accept assignment, the physician may collect his or her usual charge for the administration of the vaccine, but may not collect any fee upfront for the vaccine. The non-participating physician, provider or supplier must accept the

Medicare approved amount. The influenza and PPV vaccines are subject to mandatory assignment regardless of whether the physician normally does not accept assignment.

C.9 May providers, physicians, and suppliers charge and collect payment from Medicare beneficiaries for the influenza or PPV vaccinations?

Non-participating physicians, providers, and suppliers that do not accept assignment on the administration of the vaccines may collect payment from the beneficiary, but they **must submit an unassigned claim on the beneficiary's behalf**. All physicians, non-physician practitioners and suppliers must accept assignment for the Medicare vaccine payment rate and may not collect payment from the beneficiary for the vaccine.

Participating physicians, non-physician practitioners, and suppliers that accept assignment must bill Medicare if they charge a fee to cover any or all costs related to the provision and/or administration of the influenza or PPV vaccine. They may not collect payment from beneficiaries.

C.10 May a physician, provider, or supplier charge a Medicare beneficiary more for an immunization than he or she charges a non-Medicare patient?

No. According to Section 1128(b) (6) (A) of the Social Security Act, a physician/supplier may not charge a Medicare beneficiary more for an immunization than they would charge a non-Medicare patient. (For exceptions to this rule, see C15)

C.11 There has been some concern about the confusion caused by providers advertising influenza and PPV vaccination as “free.” When patients later receive Medicare Summary Notices (MSNs), they contact the carrier to report fraudulent billing. Should providers advertise this as a “free” service?

Participating physicians, providers, and suppliers that accept assignment may advertise that there will be no charge to the beneficiary, but they should make it clear that a claim will be submitted to Medicare on their behalf.

Non-participating physicians, providers, and suppliers that do not accept assignment for the service of administering the vaccine should never advertise the service as free since there could be an out-of-pocket expense for the beneficiary after Medicare has paid at 100 percent of the Medicare-allowed amount.

C.12 Is a coinsurance amount or deductible required for the influenza and PPV vaccine benefits?

No. Medicare pays 100 percent of the Medicare approved charge or the submitted charge, whichever is lower. Neither the \$124 annual Part B deductible nor the 20 percent coinsurance applies.

C.13 May a physician, provider or supplier collect payment for an immunization from a beneficiary and instructs the beneficiary to submit the claim to Medicare for payment?

No. Section 1848 (g) (4) (A) of the Social Security Act requires that physicians, providers, and suppliers submit a claim for services to Medicare on the beneficiary's behalf.

C.14 How should carriers handle influenza vaccine or PPV claims that are submitted by beneficiaries?

Though Section 1848(g) (4) (A) of the Social Security Act requires physicians and suppliers to submit Part B Medicare claims for beneficiaries for services furnished on or after September 1, 1990, carriers should accept and process claims submitted by beneficiaries under procedures that are applied in other situations in which unassigned claims submitted on Form CMS-1490s are received from beneficiaries. Carriers should use the provider specific information included on receipts submitted by beneficiaries to construct a skeleton provider record and assign a temporary provider number for the entity that furnished the service. Carriers should need minimal information to assign a provider number and assign a temporary provider number for the entity that furnished the service. Carriers should need minimal information to assign a provider number and establish/create a provider file record.

Carriers should also initiate appropriate educational contacts with the providers concerning Medicare billing requirements for Part B services covered, obtain a formal provider application, and assign a provider identification number.

C.15 May providers, physicians, and suppliers submit claims for the influenza and PPV benefit to Medicare if they provide the benefits free of charge or on a sliding fee scale to other patients?

Non-governmental entities (providers, physicians, or suppliers) that provide immunizations free of charge to all patients, regardless of their ability to pay, must provide the benefit free of charge to Medicare beneficiaries and may not bill Medicare.

However, a non-governmental entity that does not charge patients who are unable to pay, or reduces its charge for patients of limited means (sliding fee scale), but does expect to be paid if a patient can afford or has health insurance which covers the items or services provided, may bill Medicare and receive Medicare program payment.

State and local government entities, such as public health clinics, may bill Medicare for immunizations given to beneficiaries even if they provide immunizations free to all patients, regardless of their ability to pay.

C.16 Historically, some entities that have provided mass immunization programs have not charged patients the full cost of the vaccine and/or its administration

because they have subsidized part of the cost from their budgets. Instead, they have requested a specific dollar “donation” that covers part of the cost of the vaccination. These entities do not then submit a claim to Medicare on behalf of the beneficiary. Is this an acceptable practice?

No. Since the influenza and PPV vaccine benefits do not require any beneficiary coinsurance or deductible, a Medicare beneficiary has a right to receive this benefit without incurring any out-of-pocket expense. In addition, the entity is required by law to submit a claim to Medicare on behalf of the beneficiary.

The entity may bill Medicare for the amount that is not subsidized from its budget. For example, an entity that incurs a cost of \$7.50 per influenza vaccination and pays \$2.50 of the cost from its budget may bill the carrier the \$5.00 cost which is not paid out of its budget.

C.17 Must carriers generate the MSN for beneficiaries for the influenza and PPV vaccinations?

An MSN must be generated for influenza and PPV vaccines and their administration.

C.18 Will Medicare pay for claims for influenza and PPV vaccinations that are old?

Immunizers have at least 27 months from the date of service to file claims to the Medicare Program. All claims not submitted within the first 12 months, however, will have a 10% reduction in payment that cannot be passed on to the Medicare beneficiary.
Billing Procedures

General Billing Procedures

(See Section D for Roster Billing procedures)

C.19 What information is needed on the CMS-1450 and CMS-1500 to bill for the influenza and PPV vaccinations?

All data fields that are required for any Part A or Part B claim are required for the vaccines and their administration. Physicians, non-physician practitioners, and suppliers should bill in accordance with the instructions within provider manuals provided by their Medicare carrier. Additionally, coding specific to these benefits is required. The forms are available online at http://new.cms.hhs.gov/ElectronicBillingEDITrans/15_1450.asp.

Institutional providers should bill in accordance with the instructions within provider manuals provided by their Medicare FI.

C.20 If the Health Insurance Claim Number (HICN) is incorrect, will the contractor contact the provider or the beneficiary to determine the correct number?

Providers and suppliers are responsible for filling out required items on the claims forms with correct information from beneficiaries. If necessary, the “Date of Birth” column on the roster should, along with other data elements, provides sufficient beneficiary information for the contractor to resolve incorrect HICNs. However, if through other information on the claim or through beneficiary contact the contractor cannot resolve the problem, the claim will be rejected.

Health Insurance Portability and Accountability Act (HIPAA)

C.21 What is HIPAA?

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 are intended to reduce the costs and administrative burdens of health care by making possible the standardized, electronic transmission of many administrative and financial transactions that are currently carried out manually on paper. HIPAA is the first step toward building an e-commerce platform for exchanging health care information and will improve the effectiveness and efficiency of the health care industry in general, by simplifying the administration of the system and enabling the efficient electronic transmission of certain health information.

C.22 Who/what is a “covered entity” for HIPAA?

To determine whether you are a covered entity, go to the CMS website at <http://www.cms.hhs.gov/HIPAAGenInfo/>, http://www.cms.hhs.gov/HIPAAGenInfo/06_AreYouaCoveredEntity.asp#TopOfPage, or call the HIPAA Administrative Simplification Hotline at 1-866-282-0659. All health plans, health care clearinghouses, and providers who transmit health information electronically are classified by HIPAA as covered entities. These include physicians, dentists, pharmacies, nursing homes, hospitals, hospices, DMEs, home health agencies, and others.

C.23 What impact does HIPAA requirements have on influenza and PPV billing?

Note that paper claims for influenza and PPV are exempt from having to be submitted electronically (see C.31). HIPAA Administrative Simplification required all “covered entities” that transmit any health information in electronic form to comply with the regulations regarding standard electronic transactions and code sets by October 16, 2003. CMS will focus on obtaining voluntary compliance and use a complaint-driven approach for the enforcement of HIPAA’s electronic transactions and code sets provisions. In July 2003, HHS issued guidance regarding the enforcement of the HIPAA transactions and code set standards after October 16, 2003. The guidance clarified that covered entities, which make a good faith effort to comply with HIPAA electronic transaction and code set standards, may implement contingencies to maintain operations and cash flow. Specifically, as long as a health plan demonstrates its active outreach and testing efforts, it can continue processing payments to providers.

C.24 How long will paper claims for influenza and PPV continue to be paid by Medicare?

For non-centralized billers, paper claims for Medicare-covered vaccinations are now exempt from the electronic submission requirement under a ruling published August 15, 2003.

C.25 Where can we find additional information related to HIPAA?

Information about HIPAA and its requirements is available through CMS, industry groups, associations, and other organizations:

Web sites:

<http://www.cms.hhs.gov/HIPAAGenInfo/> – Website for Centers for Medicare & Medicaid Services (CMS)
<http://aspe.hhs.gov/admsimp/index.shtml> – DHHS Administrative Simplification Website
<http://www.wpc-edi.com/hipaa> and <http://www.hipaa-dsmo.org/> – Washington Publishing Company, download free implementation guides, Q&As, etc.
Email: AskHIPAA@cms.hhs.gov – ask questions of the CMS HIPAA experts
Telephone: HIPAA Administrative Simplification Hotline, 1-866-282-0659
Questions regarding HIPAA privacy requirements should be directed to the U.S. Department of Health & Human Services Office for Civil Rights, 1-866-627-7748 or its website at <http://www.hhs.gov/ocr/hipaa>.

C.26 If a physician sees a beneficiary for the sole purpose of administering a influenza or PPV vaccination, may they routinely bill for an office visit?

No. If a physician sees a beneficiary for the sole purpose of administering an influenza or PPV vaccination, the physician may only bill for the administration and vaccine. However, if a patient actually receives reasonable and medically necessary services constituting an “office visit” level of service, the physician may bill for the office visit, the vaccine and the administration of the vaccine.

C.27 Can providers bill for services related to counseling and education?

No. Medicare does not pay solely for counseling and education for influenza and PPV vaccines. . If Medicare-covered services are provided during the visit in which the immunization is given, the physician may code and bill those other medically necessary services, including evaluation and management services. A frequently asked question (FAQ) section on the CMS website describes the use of these codes in detail.

C.28 Does HHAs apply to other Part A Providers?

Yes. They apply to providers who bill the FI.

C.29 For HHAs, are vaccines paid under cost reimbursement?

Yes. Medicare pays for vaccine on a cost-reimbursement basis on the cost report.

C.30 If a vaccine (influenza, PPV, or Hepatitis B) is administered during the course of an otherwise covered home health visit (e.g., to perform wound care), is the visit covered by Medicare? If so, how should it be billed?

Yes, the visit would be covered as normal, but the HHA must not include the vaccine or its administration in their visit charge. In this case, the HHA is entitled to payment for the vaccine and its administration under the vaccine benefit. In this situation, the HHA bills under bill type 34X and reports revenue code 0636 along with the appropriate HCPCS code for the vaccine and revenue code 0771 along with the appropriate HCPCS code for the administration.

C.31 For HHAs, will interim rates be paid to home health agencies for their immunization expenses?

Yes. Provider Reimbursement Manual, Part 1, section 2406, provides for the percentage of billed charges interim payment method for cost reimbursed services by HHAs. As this section explains, the intermediary, with documentation from the HHA, estimates the annual Medicare cost-reimbursement for the vaccines furnished to beneficiaries divided by estimated charges for those drugs, applying the resulting interim rate to the vaccine charges on submitted bills. Although the lower of costs or charges provision does not apply to an HHA's Medicare prospective payments, it does apply to items or services paid on a cost basis. Therefore, should the estimated charges for the vaccines be less than estimated cost, the interim rate cannot exceed 100 percent (section 2406.6). Interim payments are to be approximated as close as possible to the reimbursement that will be made on the cost report. Therefore, an intermediary is expected to monitor the rate and make adjustments as necessary, and a provider may always furnish information to its intermediary if it can support that the actual costs are significantly different from the payment it is receiving via its interim payments. Finally, adjustment is made with a payout or recovery as necessary on final settlement (and, as appropriate, through a tentative retroactive adjustment on the submitted cost report).

C.32 How should HHAs represent the costs for vaccines and administration on their cost reports? (Further guidance is provided at B.23)

The cost of the vaccines is shown separately on the cost report (for free-standing HHA on FORM CMS-1728, Worksheet A, line 13, Drugs, later further identified On Worksheet C between drugs to which Medicare deductible and coinsurance (D&C) apply (the osteoporosis drug) and drugs to which D&C do not apply (influenza and pneumococcal vaccines)). Provider documentation to support the costs incurred is no different than for any other cost claimed on the cost report or different from what has been expected for these vaccines in the past. An HHA must have support for its costs when asked by the FI

for that information. Administration of the vaccines during a visit made for reasons other than administration of a vaccine is part of the visit cost paid under the Prospective Payment System (PPS) and is not paid separately. The cost of administration made outside the context of home health visits and which is documented as necessary in administering the vaccines can be included in the drugs cost center along with the vaccine cost. Cost finding (allocation of overhead costs) is done the same as for any other cost center, whether paid via PPS or on a cost basis. Statistics for the drugs cost center will draw overhead (general service) costs as appropriate. For example, the accumulated cost statistic draws administrative and general costs, and the square footage statistic draws capital and plant operation costs as appropriate.

C.33 Are there any specific reasonable cost limits or guidelines applied to vaccination costs that could result in payments less than a HHA's actual costs for furnishing services to Medicare beneficiaries?

Other than application of the lower of costs or charges provision, Medicare recognizes the reasonable, allowable cost for vaccines. If an HHA's intermediary believes that the HHA has unreasonably incurred cost for the vaccines—or otherwise has not been a prudent buyer—it is up to the HHA to support that it was prudent and that the costs are reasonable. If it cannot, the intermediary is expected not to recognize what it finds to be the unreasonable portion of the incurred cost.

C.34 If vaccine demand is less than that anticipated, and vaccine cannot be returned, resold or used elsewhere, may the cost of unused vaccine be considered as a reasonable cost?

No. CMS would only pay for vaccines actually administered. We would not pay for vaccines bought by hospitals or HHAs but never administered. For instance, a provider may order 1,000 vaccines but only provide 700 immunizations because of lower than anticipated demand. CMS would recognize only the cost of the 700 vaccines that are administered. We would not recognize the cost of the 300 excess unused vaccines.

PART A – Fiscal Intermediaries

C.35 Who bills for influenza and PPV vaccination when it is furnished to a dialysis patient of a hospital or hospital-based renal dialysis facility?

When vaccination is furnished to a dialysis patient of a hospital, the hospital bills the intermediary using bill type 12x and Tob 13x. For dialysis patients of a hospital-based or independent renal dialysis facility, the facility bills under 72x.

C.36 What bill types for claims billed to the intermediary are applicable for influenza and PPV vaccine benefits?

Applicable bill types are: 12x, 13X, 22X, 23X, 34X, 72X, 75X, 83X and 85X. RHCs/FQHCs do not bill the intermediary for the influenza and pneumococcal vaccinations. Payment is made based on information provided on the cost report.

C.37 Generally, RHCs and FQHC are required to use revenue code 52x or 0900 in order to bill. How should they code for the influenza and pneumococcal vaccines and their administration on the CMS-1450?

RHCs and FQHCs do not include charges for the influenza and pneumococcal vaccines or their administration on the CMS-1450. Payment is made at cost settlement.

C.38 For claims billed to the intermediary, are providers allowed to use therapy revenue codes on the influenza vaccine and PPV claims?

Providers bill for the vaccines using revenue code 636, and for the administration using revenue code 771. If therapy services are also provided, they can be reflected on the same claim with the vaccines and their administration.

C.39 Should shared systems maintainers allow condition code “A6” or special program indicator “06” on vaccine claims?

Yes. Condition code A6 is used to indicate services not subject to deductible and coinsurance.

C.40 For inpatient hospital and SNFs that bill the intermediary, what revenue code is used for the administration?

All providers that bill the intermediary for the influenza and PPV vaccines report the administration under revenue code 771.

C.41 What bill types do hospitals and SNFs that bill the intermediary report for inpatients that receive this benefit?

Medicare hospitals bill for the vaccines under bill type 12x for their inpatients and SNFs bill for the vaccines under bill type 22x.

PART B – Carriers

C.42 What should be entered in item 11 of the CMS-1500 when Medicare is known to be the secondary payer?

For all influenza vaccination claims submitted to a carrier, item 11 (Insured’s Policy Group or FECA Number) of the preprinted CMS-1500 should show “NONE.”

C.43 Sometimes an entity receives donated vaccine or receives donated services for the administration of the vaccine. In these cases, may the provider bill Medicare for the portion of the vaccination that was not donated?

Yes.

C.44 Is a Unique Provider Identification Number (UPIN) required on the CMS-1500 for Influenza and PPV claims?

As a physician's order is no longer required for PPV vaccinations, the UPIN of the physician is no longer required on the CMS-1500.

Diagnosis and Procedure Codes

C.45 What are the specific codes that must be used?

The following codes are used for influenza vaccinations:

CPT/HCPCS Code	<u>Description</u>
90655	Influenza virus vaccine, split virus, preservative free , for children 6-35 months of age, for intramuscular use
90656	Influenza virus vaccine, split virus, preservative free, for use in individuals 3 years and above, for intramuscular use.
90657	Influenza virus vaccine, split virus, for children 6-35 months of age, for intramuscular use
90658	Influenza virus vaccine, split virus, for use in individuals 3 years of age and above, for intramuscular use

90659	Influenza Virus Vaccine, Whole Virus, for Intramuscular or Jet injections use (Discontinued 12/31/2003)
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90660	Influenza vaccine, live, for intranasal use
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G0008	Administration of influenza virus vaccine
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Diagnosis Code	<u>Description</u>
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V04.8	Influenza vaccination with dates of service prior to 10/01/2003
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V04.81	Influenza vaccination with dates of services 10/1/2003 and later
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V06.6	PPV and Influenza (Effective October 1, 2006, providers may report diagnosis code V06.6 on claims for PPV and/or Influenza
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Virus vaccines when the purpose of the visit was to receive both vaccines

Providers are responsible for submitting the correct codes on their claims. The code should be chosen based on the description of the drug and the age of the patient. Codes are not interchangeable.

The following codes are used for PPV vaccinations:

CPT/HCPCS Code	<u>Description</u>
90732	Pneumococcal polysaccharide vaccine, 23-valent, adult or immunosuppressed patient dosage, for use in individuals 2 years or older, for subcutaneous or intramuscular use
G0009	Administration of pneumococcal vaccine when no physician fee schedule service on the same day.

Diagnosis Code	Description
V03.82	Pneumococcal Vaccination

C.46 If a beneficiary receives both an influenza and PPV vaccine on the same day, will Medicare pay twice for the administration fee?

Yes, as long as you indicate the appropriate codes for administration. Providers not roster billing may put both vaccine and their administration on the same form.

C.47 May other charges be listed on the same bill with the influenza and PPV vaccinations?

For normal billing procedures (not roster billing), other charges may be listed on the same bill as influenza and PPV vaccinations. However, there must be separate coding for the additional charge(s).

C.48 If we choose not to roster bill and only bill on the UB 92, will Medicare track the usage from the revenue code?

Medicare will track using HCPCS and revenue codes on the UB-92.

C.49 As a provider, if I choose not to roster bill and only bill on the UB-92, will Medicare track the usage from the revenue code 771?

HCPCS codes would be used to track vaccine services regardless of whether they are billed on a roster or UB. The intermediary converts all rosters to UBs. The revenue code alone would not provide sufficient information to identify the vaccine.

C.50 I noticed on a recent Medicare bulletin that vaccines are no longer reimbursed under OPPS, but are reimbursed according to reasonable cost. How will the reimbursement be calculated?

Each provider is assigned an interim rate which is applied to charges for items subject to reasonable cost reimbursement and that is the amount that is payable on an interim claim by claim basis. Final payment is then made via the cost settlement.

D. Mass Immunizers/Roster Billers

Note: Although these questions primarily concern mass immunizers, they may apply to any entity immunizing Medicare beneficiaries.

Definition

D.1 What is a mass immunizer?

As used by CMS, the term “mass immunizer” is defined in the following manner:

- A mass immunizer generally offers influenza and/or PPV vaccinations to a large number of individuals (the general public or members of a specific group, such as residents of a retirement community).
- A mass immunizer may be a traditional Medicare provider or supplier such as a hospital outpatient department or may be a nontraditional provider or supplier such as a senior citizen’s center, a public health clinic, community pharmacy or supermarket.
- A mass immunizer submits claims for immunizations on roster bills.
- Mass immunizers must accept assignment.

Enrollment Requirements

Note: This enrollment process currently applies only to entities that will (1) bill a carrier; (2) use roster bills; and (3) bill only for influenza and/or PPV vaccinations.

D.2 Do providers and suppliers that want to mass immunize and submit claims to Medicare on roster bills have to enroll in the Medicare program?

Yes. Providers and suppliers must enroll in Medicare even if mass immunizations are the only service they will provide to Medicare beneficiaries.

Providers and suppliers who will not provide other covered services to Medicare beneficiaries complete only the portion of the enrollment form that applies to mass immunizers.

Providers and suppliers who wish to roster bill for mass immunizations should contact the Medicare carrier servicing their area for a copy of the enrollment application and special instructions for mass immunizers. Those entities will enroll as provider specialty type 73, Mass Immunization Roster Biller. As such, they will accept assignment on both the administration and the vaccine. Entities providing mass immunizations must enroll

by filling out Form CMS-855-I at <http://www.cms.hhs.gov/CMSforms/downloads/cms855i.pdf> for individuals or Form CMS 855-B at <http://www.cms.hhs.gov/CMSforms/downloads/cms855b.pdf> to enroll as a group. A list of carriers and their contact information can be found at http://www.cms.hhs.gov/ContractingGeneralInformation/Downloads/02_ICdirectory.pdf.

D.3 If a provider or supplier already has a Medicare provider number for non-immunization services that they provide (i.e., DME), do they need to obtain a new provider number in order to use the roster billing process for the influenza and/or PPV services that they provide?

No. Providers and suppliers may use their existing provider numbers and use the roster billing process as long as they provide the influenza vaccine and/or PPV service to multiple beneficiaries and agree to accept assignment on the service.

D.4 Does a corporate entity with numerous locations have to get a Medicare provider number for each location?

Reimbursement for the administration of the influenza and PPV vaccines is based on the locality of the provider. Therefore, if the practice locations were in different payment localities, then it would be necessary for each to obtain a separate Medicare provider number for each practice location. The only exception to this is an entity that participates in the Centralized Billing program.

D.5 Can providers who conduct immunization activities within their community (outside of their main practice site) utilize their practice's provider number if they are operating at those sites under the auspices of their practice?

Yes.

D.6 Why enroll providers if they are going to provide mass immunizations to Medicare beneficiaries only once a year?

Although CMS wants to make it as easy as possible for providers and suppliers to immunize Medicare beneficiaries and bill Medicare, it must ensure that those providers who wish to enroll in the Medicare program are qualified providers, receive a provider number, and receive the proper payment.

D.7 May a company or representative sign the applications, or does it have to be the president who signs all of the applications?

Only an authorized or delegated official may sign the CMS 855B application. The authorized official can be the owner or a person with a managing interest in the organization. The authorized officials must be listed in Section 6 of the CMS 855B. The owner or authorized official for the organization is required to submit their social security number in Section 6. The owner or authorized official carries the legal responsibility for

actions taken by the organization. The authorized official can designate a delegated official to perform Medicare enrollment activities. A delegated official must be either a W2 managing employee of the organization, an individual with 5% or greater ownership interest in the organization or in a partnership with the enrolling entity. The owner or authorized official must notify Medicare of any delegated officials in Section 16 of the CMS 855B. Only the owner, authorized official or delegated official has the authority to enroll an organization or make changes to an established enrollment record. Only the owner, authorized official or delegated official may sign the CMS 855 application.

D8. Is a separate number required for each site, or can a corporation have one number?

A corporation must have one number for each payment locality. Corporations who will centrally bill can have one number. The corporation is required to complete Item 32 on the CMS-1500 paper claim form or equivalent form for electronic claims filers. The claim is paid through the use of zip codes and allowances are based on locale where services are furnished.

D.9 Do Regional Home Health Intermediaries (RHHIs) accept roster bills from HHAs?

Yes.

D.10 If a hospital has an outpatient unit, like a pharmacy, that wishes to administer vaccines, how should it bill for the vaccine and supplies – through the hospital number or should it get a separate number?

The pharmacy is still part of the hospital, and should follow the roster billing instructions in the IOM for billing to the FI.

Billing Procedures

D.11 What impact does HIPAA requirements have on electronic Mass Immunizer Roster Billing?

Roster billing is a streamlined process for submitting health care claims for large groups of individuals usually for influenza and/or PPV vaccinations for which HIPAA adopted an electronic standard, the ASC X12N 837. Roster billing can be done electronically or via paper. When conducting roster billing electronically, mass immunizer providers are required to use the HIPAA-adopted ASC X12N 837 claim standard.

D.12 Can roster billing be conducted on paper?

Paper claims for Medicare-covered vaccinations are now exempt from the HIPAA electronic billing requirement under a ruling published August 15, 2003.

D.13 Is electronic billing available for roster-billed claims?

Not all contractors offer electronic roster billing software. However, if available, contractors should offer low or no-cost software for providers to use when roster billing electronically. Providers should confirm with their local carrier if electronic roster billing software is available.

D.14 How many beneficiaries per day must be vaccinated in order for the roster billing procedure to be used?

Generally, **FOR INTERMEDIARY PROCESSED CLAIMS ONLY**, five beneficiaries per day must be vaccinated in order to roster bill. However, this requirement is waived for inpatient hospitals that mass immunize and utilize the roster billing method.

Effective July 1, 1998, **CARRIER PROCESSED CLAIMS ONLY**, immunization of at least five beneficiaries on the same date is no longer required for any individual or entity to qualify for roster billing. However, the rosters should not be used for single patient bills and the date of service for each vaccination administered must be entered. (DATE OF SERVICE)

D.15 Can a roster bill have different dates of service?

No.

D.16 If providers/suppliers enroll in Medicare for the purpose of roster billing for mass immunizations only, may they bill Medicare for other Part B services?

No. Providers/suppliers who wish to bill for other Part B services must enroll as a regular provider or supplier by completing the entire CMS-855.

D.17 Can mass immunizer's bill for services relating to counseling and education?

No. Mass immunizers are a provider-type created under Medicare solely to facilitate mass immunization, not to provide other services. (Physicians may bill for additional medically necessary services but not on the roster bill. See C22.)

D.18 May an individual or entity providing both influenza and PPV vaccinations to the beneficiaries submit a single CMS-1450 or CMS-1500 that contains the information for both the influenza and PPV vaccinations and a single roster bill that contains the names of the beneficiaries who received both vaccinations?

No. Individuals and entities submitting claims for influenza and PPV vaccinations must submit a separate CMS-1450 or CMS-1500 for each type of vaccination. Each CMS-1450 or CMS-1500 must have an attached roster bill listing the beneficiaries who received that type of vaccination. Each roster bill must also contain all other information required on a roster bill.

D.19 Are the roster bills used for influenza and PPV vaccinations identical?

No. The following reminder to providers must be printed on the PPV roster bill:

WARNING: Ask beneficiaries if they have been vaccinated with PPV.

Rely on patients' memory to determine prior vaccination status.

If patients are uncertain whether they have been vaccinated within the past 5 years, administer the vaccine.

If patients are certain they have been vaccinated within the past 5 years, do not revaccinate.

D.20 What blocks on the CMS-1500 can be preprinted for providers using roster billing for influenza and/or PPV vaccine and/or administration claims?

The following blocks can be preprinted on a modified CMS-1500 form:

Item 1: An X in the Medicare block

Item 2: (Patient's Name): "SEE ATTACHED ROSTER"

Item 11: (Insured's Policy Group or FECA Number): "NONE"

Item 20: (Outside Lab?): An "X" in the "NO" block

Item 21: (Diagnosis or Nature of Illness):

Line 1: (only one code, not both)

PPV: "V03.82"

Influenza Virus: "V04.81"

Item 24B: (Place of Service (POS)):

Line 1: "60"

Line 2: "60"

NOTE: POS code "60" must be used for roster billing

Item 24D: (Procedures, Services or Supplies):

Line 1:

PPV: "90732"

Influenza Virus: "90658"

Line 2: (only one code, not both)

PPV: "G0009"

Influenza Virus: "G0008"

Item 24E: (Diagnosis Code):

Lines 1 and 2: "1"

Item 24F: (\$ Charges): The entity must enter the charge for each listed service. If the entity is not charging for the vaccine or its administration, it should enter 0.00 or "NC" (no charge) on the appropriate line for that item.

Item 27: (Accept Assignment): An "X" in the YES block

Item 29: (Amount Paid): "\$0.00"

Item 31: (Signature of Physician or Supplier): The entity's representative must sign the modified form CMS-1500.

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- Item 32: (Name and Address of Facility): N/A
- Item 33: (Physician's, Supplier's Billing Name): If the provider number is not shown on the roster billing form, the entity must complete this item to include the Provider Identification Number (not the Unique Provider Identification Number) or Group Number as appropriate.

D.21 Do providers show the charge for one service or the total for all patients in block 24F of the modified CMS-1500?

Providers should show the unit cost, since carriers will have to replicate the claim for each beneficiary listed on the roster.

D.22 What information needs to be submitted on a patient roster form that will be attached to a preprinted CMS-1500 under the roster billing procedure?

The following should be included on the roster form: Patient Name and Address; Health Insurance Claim Number; Date of Birth; Sex; Date of Service; Signature or stamped "Signature on File"; and Provider's Name and Identification Number; and control number for the contractor.

Some carriers allow providers/suppliers to develop their own patient roster forms that contain the minimum data as reflected above, while others do not. Providers/suppliers should contact their carrier to learn their particular carrier's practice regarding patient roster forms.

D.23 What is the meaning of "signature on file?"

For all institutional providers that roster bill from inpatient or outpatient departments, and for all other providers outside of the institutional setting that roster bill, a stamped "signature on file" qualifies as an actual signature on a roster claim form provided that the provider has a signed authorization on file to bill Medicare for services rendered. In this situation, the provider is not required to obtain the patient signature on the roster, but instead has the option of reporting "signature on file."

D.24 May hospitals and other entities that bill intermediaries use the "signature on file" designation on a roster bill?

Yes. Inpatient/outpatient departments of hospitals and outpatient departments of other providers may use a signature on file stamp or notation if they have access to a signature on file in the beneficiary's record.

D.25 What would the carrier do if a roster bill were received incomplete or incorrect?

The carrier would deny or reject the claim as unprocessable.

D.26 May other services be listed along with the influenza or PPV vaccine and administration on the modified CMS-1500?

No. Other covered services are subject to more comprehensive data requirements, which the roster billing process is not designed to accommodate. Other services should be billed using normal Part B claims filing procedures and forms.

D.27 What place of service code should be used for PHCs that bill carriers for the influenza and PPV vaccines and their administration?

PHCs should use place of service code “60,” public health or welfare agencies (federal, state, and local), if roster billing. If not roster billing, PHC POS is 71.

D.28 If a beneficiary receives influenza or PPV vaccination shot at a mobile unit brought to a senior center or parking lot of a mall, what place of service code should be used?

A PHC-affiliated mobile unit should use POS code “71” unless vaccinations are administered in a mass immunization setting. ALL entities that administer vaccinations in a mass immunization setting should use POS code “60” (Mass Immunization Center), no matter the setting. A mobile unit not affiliated with a PHC and not acting as a mass immunization setting should use “99” (other).

D.29 In some instances, two entities, such as a grocery store and a pharmacy, jointly sponsor a vaccination clinic, and each is reluctant to accept responsibility for billing. What are the criteria for determining the responsible party?

Assuming that a charge is made for both the vaccine and its administration, the entity that furnishes the vaccine and the entity that administers the vaccine are each required to submit claims. Both parties must file separately for the specific component furnished for which a charge was made.

When billing only for the administration, billers should indicate in block 24 of the CMS-1500 that they did not furnish the vaccine. For roster billed claims, this can be accomplished by lining through the preprinted item 24 line item component that was not furnished by the billing entity or individual.

Hospital Inpatient Roster Billing

D.30 Some hospitals have concerns about reimbursement for influenza and pneumococcal vaccines administered during hospitalization. Are these vaccinations covered by the DRG flat rate, or reimbursed separately?

Since influenza and pneumococcal vaccines are covered under Part B benefit, they are not paid above the DRG but paid under Part B when billed on a 12X type of bill for inpatients vaccinated in the hospital. For both vaccines, hospitals may roster bill for the vaccine and its administration. There is no co-pay or deductible for either vaccine.

D.31 If a hospital has an outpatient unit, like a pharmacy, that wishes to administer vaccines, how should it bill for the vaccine and supplies – through the hospital number or should it get a separate number?

The pharmacy is still part of the hospital, and should follow the roster billing instructions in the IOM for billing to the Fiscal Intermediary (FI).

D.32 What is the procedure for billing inpatient vaccinations?

All instructions are in the IOM Pub 100-4, Chapter 18, and Section 10.2.

A hospital can bill for an inpatient of a hospital using a 12x bill type using the date of discharge as the date the vaccine and its administration was given. This will avoid editing in CWF. You may also roster bill in a hospital inpatient setting. There are certain criteria for that:

1. You do not have to wait until patients are discharged.
2. Roster should reflect the actual date of service.
3. Requirement to provide the vaccine to five or more patients at the same time to meet the requirement for mass immunizers will be waived when vaccines are provided to inpatients. The roster may contain fewer than 5 patients or fewer than 5 patients on the date of discharge and the roster must contain information indicating that the vaccine was provided to inpatients to avoid questioning regarding the number of patients or various dates.

E. Centralized Billing

E.1 What is centralized billing?

Centralized billing is a process in which a provider, who is a mass immunizer for influenza and PPV immunizations, can send all such claims to a single carrier for payment regardless of the geographic locality in which the vaccination was administered.

To qualify for centralized billing, a mass immunizer must be operating in at least three payment localities for which there are three different carriers processing claims. Individuals and entities providing vaccine and administration of vaccine must be properly licensed in the State in which the immunizations are given. It's the provider's responsibility to ascertain and meet all State licensure requirements for each State where they plan to provide these services.

E.2 Do I have to enroll as a different provider type to participate in the centralized billing program?

Yes. Individual and entities that wish to participate in the centralized billing program must enroll as a Mass Immunizer Roster Biller even if they are already enrolled in Medicare as another provider type.

E.3 How is claims that are submitted through the centralized billing program reimbursed?

The administration of the vaccinations will be reimbursed per the Medicare Physician Fee Schedule (MPFS) for the appropriate locality. The vaccines will be reimbursed at the standard method used by Medicare Part B for reimbursement of drugs and biologicals, which is the lower of the charge or 95 percent of the Average Wholesale Price (AWP).

E.4 How can I participate in this program?

Multi-state mass immunizers interested in centralized billing must contact CMS Central Office (CO) in writing at the following address by June 1 of each year in order to participate in this program for the upcoming influenza season.

**Division of Practitioner Claims Processing
Provider Billing and Education Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Mail Stop C4-10-08
Baltimore, MD 21244
Attention: Bridgitte Davis
410-786-4573**

E.5 Is there any particular information that is required in the written request to participate in the centralized billing program?

Yes, the information requested below must be included with the multi-state mass immunizer's request to participate in centralized billing:

- Estimates for the number of beneficiaries who will receive influenza vaccinations;
- Estimates for the number of beneficiaries who will receive PPV vaccinations;
- The approximate dates for when the vaccinations will be given;
- A list of the states in which influenza and PPV clinics will be held;
- The type of services generally provided by your corporation (e.g., ambulance, home health, or visiting nurse); and,
- Whether the nurses who will administer influenza and PPV vaccinations are employees of your corporation or will be hired by your corporation specifically for the purpose of administering influenza and PPV vaccinations.

E.6 Is there a particular carrier that centralized billing claims should be submitted to?

Yes. Upon acceptance into the program as a centralized biller, you will be provided with contact information for the carrier that will be processing the claim.

E.7 Are there any specific criteria associated with centralized billing?

Yes, by agreeing to participate in the centralized billing program, providers agree to abide by the following criteria:

- A mass immunizer must be operating in at least three payment localities for which there are three different carriers processing claims.
- Individuals and entities providing the vaccine and administration must be properly licensed in the state in which the immunizations are given.
- Multi-state mass immunizers must agree to accept assignment (i.e., they must agree to accept the amount that Medicare pays for the vaccine and the administration). Since there is no coinsurance or deductible for the influenza and PPV benefit, accepting assignment means that Medicare beneficiaries cannot be charged for the vaccination, i.e., beneficiaries may not incur any out-of-pocket expense. For example, a drugstore may not charge a Medicare beneficiary \$10 for an influenza vaccination and give the beneficiary a coupon for \$10 to be used in the drugstore. This practice is unacceptable.
- The carrier assigned to process the claims for centralized billing will be chosen at the discretion of CMS based on such considerations as workload, user-friendly software developed by the contractor for billing claims, and overall performance.
- The payment rates for the administration of the vaccinations will be based on the MPFS for the appropriate year. Payment made through the MPFS is based on geographic locality. Therefore, the multi-state mass immunizer must be willing to

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- accept that payments received may vary based on the geographic locality where the service was performed.
- The payment rates for the vaccines will be determined by the standard method used by Medicare Part B for reimbursement of drugs and biologicals, which is based on the lower of the charge or 95 percent of the AWP.
 - Multi-state mass immunizers must agree to submit their claims in an electronic media claims standard format using either the National Standard Format (NSF) or American National Standards Institute (ANSI) X12.837 format. Paper claims will not be accepted.
 - In addition to normal roster billing instructions, multi-state mass immunizers must complete on the electronic format, the area that corresponds to Item 32 (Name and Address of Facility, including ZIP code) on Form CMS-1500, for the carrier to be able to pay correctly by geographic locality.
 - Multi-state mass immunizers must obtain certain information for each beneficiary including name, health insurance number, and date of birth, sex, and signature. The assigned Medicare carrier must be contacted prior to the season for exact requirements. The responsibility lies with the multi-state mass immunizer to submit correct beneficiary Medicare information (including the beneficiary's Medicare Health Insurance Claim Number) since the carrier will not be able to process incomplete or incorrect claims.
 - Multi-state mass immunizers must obtain an address for each beneficiary so that the carrier can send a MSN to the beneficiary. Beneficiaries are sometimes confused when they receive an MSN from a carrier other than the carrier that normally processes their claims, which results in unnecessary beneficiary inquiries to the Medicare carrier. Therefore, multi-state mass immunizers must provide every beneficiary receiving an influenza or PPV vaccination with the name of the carrier selected by CMS. This notification must be in writing, in the form of a brochure or handout, and must be provided to each beneficiary at the time he or she receives the vaccination.
 - Multi-state mass immunizers must retain roster bills with beneficiary signatures at their permanent location for a time period consistent with Medicare regulations. The Medicare carrier selected to process the claims can provide this information.
 - Though multi-state mass immunizers may already have a Medicare provider number, for purposes of centralized billing, they must also obtain a provider number from the carrier selected by CMS to process the influenza and PPV claims. This can be done by completing Form CMS-855 (Provider Enrollment Application), which can be obtained from that carrier.
 - If a multi-state mass immunizer's request for centralized billing is approved, the approval is limited to the upcoming influenza season. It is the responsibility of the multi-state mass immunizers to reapply to the CMS CO for approval each year by June 1 for the year prior to the beginning of the influenza season for which they wish to bill. Claims submitted without approval will be denied.

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- Each year the multi-state mass immunizers must contact the assigned carrier to verify understanding of the coverage policy for the administration of the PPV vaccine, and for a copy of the warning language that is required on the roster bill.
 - The multi-state mass immunizer will be responsible for providing the beneficiary with a record of the PPV vaccination.

E.8 Are separate rosters required for each place of service as well as date of service?

No.

F. Managed Care

F.1 Can a Medicare Advantage organization (MAO) sponsor a health fair where the vaccine is provided to both their members and to Medicare beneficiaries who are not enrolled in their plan? How would they bill for the fee-for-service beneficiaries not enrolled in the MA plan?

The MA organization may furnish services to Medicare beneficiaries who are not enrolled in the prepayment plan. For services furnished to Medicare patients not enrolled in the MA plan, Medicare payment is made through the Part B carrier, outside the scope of the MA agreement with CMS.

The MAO may use roster billing if vaccinations are the only Medicare-covered services furnished by the MAO to Medicare patients who are not members of the MAO. MAO must use Place of Service (POS) code 60 for processing roster claims.

F.2 Can an MAO require their members to obtain prior authorization from their primary care provider (PCP) for influenza vaccinations?

For the influenza vaccine, enrollees can self-refer within the plan's network of providers. Enrollees under a point-of-service option within an MAO can self-refer to an out-of-network provider, consistent with the payment rules established by the MAO plan.

F.2A Can an MAO require their members to obtain prior authorization from their primary care provider (PCP) for pneumococcal vaccinations?

MA organizations can require prior approval from the enrollee's PCP to obtain the pneumococcal vaccine.

F.3 Are beneficiaries in a "lock-in" MAO plan able to receive vaccines at other locations?

Yes. Beneficiaries enrolled in MAO plans can receive influenza and PPV vaccines at other locations; however, if that location is not authorized by the MAO plan to provide shots for the MAO plan's members, the beneficiary will have to pay out-of-pocket for any fees charged for the shots

F.4 What should carriers do if providers submit claims for beneficiaries who are "locked-in" to their HMO when the vaccine is furnished by a facility or provider outside of their HMO?

Medicare will not reimburse a non-HMO provider for influenza or PPV vaccinations for beneficiaries enrolled in risk HMOs. Medicare has already paid the HMO to provide this service.

F.5 Is the beneficiary responsible for a co-payment when a vaccine is provided within the MA provider network?

For influenza vaccinations, a beneficiary may have to pay the usual co-pay for an office visit. There is no charge for the vaccine serum or for the service of giving the shot.

G. Terms and Definitions

Advisory Committee on Immunization Practices (ACIP) – The ACIP develops written recommendations for the routine administration of vaccines to pediatric and adult populations, along with schedules regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. ACIP is the only entity in the federal government that makes such recommendations.

Assignment – The doctor or person performing the service receives the Medicare payment. The provider of services accepts the amount Medicare allows as his total charge. The beneficiary is responsible for any deductible and the 20 percent coinsurance.

Assigned claim – See assignment.

Beneficiary – an individual who is entitled to Medicare Part A and/or Medicare Part B.

Billing Providers – the provider who submits a claim for payment on services he/she has performed or, in some cases, the group, such as a clinic, bills for the performing providers within the group.

Carrier – the company contracted with the federal government to handle the Medicare Part B program for a particular state.

Centers for Medicare & Medicaid Services (CMS) – the Federal agency that administers the Medicare, Medicaid and SCHIP programs.

Centralized billing – optional program for providers who qualify to enroll with Medicare as the provider type, “mass immunizer.” Additional criteria must also be met.

CMS-1450 – Paper form used to bill the fiscal intermediary for services provided to a Medicare beneficiary.

CMS-1500 – Paper form used to bill the carrier for services provided to a Medicare beneficiary.

Coinsurance – the 20 percent difference between the allowed amount and the 80 percent that is reimbursable under the Medicare program.

Deductible – the amount that must be met each calendar year from allowed medical expenses before Medicare Part B payment will be made. This amount is the responsibility of the beneficiary.

Electronic billing software – software available for transmitting electronic claims to Medicare.

Fiscal Intermediary (FI) – Contractor for the Centers for Medicare & Medicaid Services that processes claims for services covered under Medicare Part A and most types of claims for services covered under Medicare Part B.

Government entities (such as public health clinics) – may bill Medicare for PPV, hepatitis B, and influenza vaccine administered to Medicare beneficiaries when services are rendered free of charge to non-Medicare beneficiaries.

Health Care Procedure Coding System (HCPCS) – a listing of codes, modifiers, and descriptive terminology used for reporting the provision of medical supplies, materials, injections, Durable Medical Equipment (DME), prosthetic devices, and certain services and procedures to Medicare.

Health insurance claim number – the 10- or 11-digit number assigned by Medicare to each beneficiary.

Health Maintenance Organization (HMO) – a health care organization that acts both as insurer and provider of comprehensive but specified medical services. A defined set of physicians provides services to a voluntarily enrolled population for a prospective per capita amount (i.e., by capitation). Prepaid group practices and individual practice associations are types of HMOs.

Limiting charge – the limit on the amount a non-participating doctor can charge on a non-assigned claim. The limiting charge is no more than 115 percent of the fee schedule.

Managed Care Organization (MCO) – a health care organization that acts both as insurer and provider of comprehensive but specified medical services. A defined set of physicians provides services to a voluntarily enrolled population for a prospective per capita amount (i.e., by capitation). Prepaid group practices and individual practice associations are types of MCOs.

Mass Immunizer Roster Biller – provider who chooses to enroll in Medicare with this identifier, which demands the provider meets certain criteria and follows certain procedures when immunizing Medicare beneficiaries.

Medicare Summary Notices (MSNs) – the statement sent to the beneficiary explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Medically necessary – services or supplies that:

- Are proper and needed for the diagnosis or treatment of a medical condition;
- Are provided for the diagnosis, direct care, and treatment of a medical condition;
- Meet the standards of good medical practice in the medical community of the local area; and
- Are not mainly for the convenience for the patient or doctor

Non-assigned claim – a claim that directs payment to the beneficiary.

Non-government entities – entities that do not charge patients who are unable to pay or reduce their charges for patients of limited means, yet expect to be paid if the patient has health insurance coverage for the services provided, may bill Medicare and expect payment.

Non-participating physician/suppliers – a physician practice/supplier that has not elected to become a Medicare participating physician/supplier, i.e., one that has retained the right to accept assignment on a case-by-case basis (compare to participating physician.)

Participating physician/supplier – a physician practice/supplier that has elected to provide all Medicare Part B services on an assigned basis for a specified period of time.

Primary care physician – A physician who is trained to provide basic care. This includes being the first one to check on health problems and coordinating preventive health care with other doctors, specialists, and therapists.

Railroad Retirement Board (RRB) – an independent agency in the executive branch of the federal government. The RRB's primary function is to administer comprehensive retirement, survivor and unemployment, and sickness programs for the nation's railroad workers and their families under the Railroad Retirement & Railroad Unemployment Insurance Acts. In connection with the retirement program, the RRB has administration responsibilities under the Social Security Act for certain benefit payments for railroad workers' Medicare coverage.

Remittance Notice (RN) – the statement sent to the provider explaining how the claim was processed and what payment amount is being made, what applied to the deductible, what services were denied and why, etc.

Roster billing – (also referred to as simplified roster billing) a process developed by CMS which enables entities that accept assignment that administer the influenza and /or PPV vaccine to multiple beneficiaries to bill Medicare for payment using a modified CMS 1450, CMS-1500 claims form, or electronic software provided by Medicare carrier.

Unique Physician Identification Number (UPIN) – a number used to identify a physician in the Medicare program.

Special Thanks to Reviewers

Faith Ashby, CMS
Bridgitte Davis, CMS
Antoinette Johnson, CMM
William Larson, OCSQ
Angela Mason, CMS
William Ruiz, CMS
Gertrude Saunders, CMS
Leslie Trazzi, CMS
Dale Bratzler, Oklahoma Foundation for Medical Quality
Catherine Gordon, CDC
Tamara Kicera, CDC
Abigail Shefer, CDC
Raymond Strikas, NVPO
Mitch Rothholz, American Pharmacists Association
Debra Brigham, Trailblazer Health Enterprise, LLC

*And to others that
contributed valuable information to this document.*

If you have any questions, please contact:

Margaret Medley, CMS Dallas Regional Office, 214-767-8907
Bertha Williams, CMS Central Office, 410-786-6847
Or your
2006-2007 Regional Influenza/Pneumococcal Immunization Coordinators

**CENTERS FOR MEDICARE & MEDICAID SERVICES
2006-2007 REGIONAL INFLUENZA/PNEUMOCOCCAL IMMUNIZATION
COORDINATORS & CENTRAL OFFICE STAFF TEAM MEMBERS**

REGION/ ADDRESS	STATES	COORDINATORS	PHONE NUMBER (P) FAX NUMBER (F)
BOSTON , Region I Division of Clinical Standards and Quality 2350 JFK Federal Building Boston, MA 02203	CT, ME, MA, NH, RI & VT	Jefferson Rowland	617-565-1329 P 617-565-3856 F
NEW YORK , Region II Beneficiary Services Branch 26 Federal Plaza Room 3800 New York, NY 10469	NY, NY, PR, VI	Norma Harris Doreen Ramos Frank Winter	212-616-2342 P 212-264-2665 F 212-616-2535 P 212-264-2665 F 212-616-2355 212-264-2665
PHILADELPHIA , Region III Beneficiary Services Branch 150 South Independence Mall, W., Suite 216 Philadelphia, PA 19106	DE, DC, MD, PA, VA, WV	Melissa Herd	215-861-4778 P 215-861-4176 F
ATLANTA , Region IV Beneficiary Services Branch Sam Nunn Atlanta Federal Center 61 Forsyth Street, Suite 4T20 Atlanta, GA 30303	AL, NC, SC, FL, GA, KY, MS & TN	Charlotte Pickens Judy Weaver	404-562-7218 P 404-562-7255 F 404-562-7216 P 404-562-7255 F
CHICAGO , Region V Beneficiary Services Branch 233 N. Michigan Avenue Suite 600 Chicago, IL 60601	IL, IN, MI, MN, OH, WI	Nicholas Rodriquez	312-886-5213 P 312-886-5705 F
DALLAS , Region VI Office of the Regional Administrator 1301 Young Street, Room 714 Dallas, TX 75202	AR, LA, NM, OK, TX	Julia Lothrop Margaret Medley	214-767-6386 P 214-767-6400 F 214-767-8907 P 214-767-6323 F
KANSAS CITY , Region VII Beneficiary Services Branch Richard Bolling Federal Building 601 E. 12th Street, Room 242 Kansas City, MO 64106	IA, KS, MO, NE	Nancy Rios	816-426-6460 P 816-426-5473 F

REGION/ADDRESS	STATES	COORDINATOR(S)	PHONE/FAX
DENVER , Region VIII Beneficiary Services Branch Colorado State Bank Building 1600 Broadway, Suite 700 Denver, CO 80202	CO, MT, ND, SD, UT, WY	Lisa Dubois Mary Munoz	303-844-3521 P 303-844-3753 F 303-844-5737 P 303-844-3753 F
SAN FRANCISCO , Region IX Beneficiary Services Branch 75 Hawthorne Street, 4th Floor San Francisco, CA 94105	American Samoa, AZ, CA, NV, Guam, Hawaii	Peter W. Bauer	415-744-3664 P 415-744-3771 F
SEATTLE , Region X Beneficiary Services Branch 2201 6th Avenue Seattle, WA 98121	AK, ID, OR, WA	Ozell Bledsoe Michelle Dillon	206-615-2630 P 206-615-2363 F 206-615-2368 P 206-615-2363 F

CMS Central Office Staff:

Bertha Williams **410-786-6847, Office of Research, Development and Information**

Joanne Scheibe **410-786-5488, Office of External Affairs**

Sandra Magera **410-786-8653 Office of External Affairs**